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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/840,188

05/05/2004

Mark L. Mathis

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03/19/2009

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EXAMINER

NGUYEN, TUAN VAN

ART UNIT

PAPER NUMBER

3731

MAIL DATE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/840,188	<b>Applicant(s)</b> MATHIS ET AL.	
	<b>Examiner</b> TUAN V. NGUYEN	<b>Art Unit</b> 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 3/10/09.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-17 and 19-28 is/are pending in the application.
- 4a) Of the above claim(s) 1-16 and 21-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17, 19, 20 and 28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 May 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                        |                                                                   |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/10/09, 12/22/08, 10/2/08</u> .                              | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. In previous Office action, claims 17 and 19-20 were examined and rejected, claims 1-16 and 21-27 have been withdrawn from further consideration as being drawn to nonelected inventions and claim 18 has been cancelled.

#### ***Continued Examination Under 37 CFR 1.114***

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after the final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/10/2009 has been entered.

#### ***Response to Amendment***

3. Applicant's arguments filed on 3/10/2009 with respect to claim rejections under 35 USC § 102 and double patenting have been fully considered but they are not persuasive.
4. With respect to arguments that Solem fails to disclose new limitation as required by claim 17 is incorrect. Solem discloses (Figs. 23-25) self-expand stents 22 and 23 and the memory metal thread 20 is pushed out of the introduction sheath thereby the self-expand stents 22 and 23 expand and contact the inner wall of the

coronary sinus 24 (paragraph [0146]). Noting that the memory metal thread 20 applied a proximal force on the distal anchor as soon as the distal anchor and a portion of the memory metal thread 20 is out of the introduction sheath and the proximal anchor will be the last to leave the introduction sheath, thus, Solem discloses the step of applying a proximal directed force on the distal anchor and before the and step of expanding the proximal anchor.

5. With respect to arguments regarding double patenting rejection that claim 17 has been amended, therefore, the claim overcome the rejection has been fully considered but they are not persuasive. The double patenting rejection is maintained.
6. According to the amendment, claim 28 is new. Accordingly, claims 1-17 and 19-28 are pending in this presented application and claim 17, 19, 20 and 28 are presented for examination.

### ***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

- a. Claims 17, 19, 20 and 28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the

relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. New limitation “applying the proximally directed force on the distal anchor is initiated before the proximal anchor is expanded”, especially, the limitation of “**is initiated before** the proximal anchor is expanded” is new matter. Appropriate correction is required.

- b. Examiner interprets the limitation of, which recited in specification, “anchoring a proximal anchor before ceasing the proximally directed force” as the proximally directed force will not stop before the step of anchoring of the proximal anchor is completed.

### ***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. **Claims 17, 19, 20 and 28 are rejected under 35 U.S.C. 102(e) as being anticipated by Solem et al (U.S. 2003/0135267).**
10. Solem discloses (see Figs. 21-25) a method of changing of shape in a part of the body of an organism (see Technical Field of The Invention) the method

comprising: providing a tissue shaping device (see Fig. 21) comprising stent or proximal anchor 22, stent or distal anchor 23, a connector K/20 or focal deflector; placing the device in coronary sinus or lumen adjacent the target tissue which is the mitral valve 25, 26; expanding the stent or anchors 22, 23 to anchor the device; applying a shaping force (see Figs. 22-25) from the focal deflector against a lumen wall to modify the shape of the target tissue (see paragraphs [0139]-[0148]).

11. Referring to **claim 20**, Solem discloses (see Fig. 24) before the shaped changing member 20 is activated into the original condition the member 20 is orienting away from the target tissue.

### ***Double Patenting***

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re*

Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claim 17 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 15 of U.S. Patent No. 6,908,478 to Alferness et al. Claim 17 recites a method of modifying target tissue shape comprising: providing a tissue shaping device comprising proximal and distal anchors, a focal deflector; placing the device in a lumen adjacent the target tissue; applying a shaping force from the focal deflector against a lumen wall to modify the shape of the target tissue; and expanding the anchors to anchor the device. It is clear that all steps of claim 17 are to be found in claim 15. Noting that claim 15 of U.S. Patent No. 6,908,478 to Alferness et al. recites a method of effecting mitral valve geometry of a heart comprising: advancing a guide catheter into the coronary sinus of the heart adjacent to the mitral valve annulus; pushing self-deploying first anchor and second anchor; providing the cable extending between first anchor and second anchor; tensioning the cable and locking the cable to the second anchor. By definition, coronary sinus is a vein, thus, it has a lumen. The

different between claim 17 of the application and claim 15 of the patent lies in the fact that the patent claim includes more elements such as the catheter and more specific such as the mitral valve and coronary sinus, thus, claim 15 is much more specific. Although the conflicting claims are not identical, they are not patentably distinct from each other.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TUAN V. NGUYEN whose telephone number is (571)272-5962. The examiner can normally be reached on M-F: 9:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, AnhTuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/T. V. N./  
Examiner, Art Unit 3731

/Anh Tuan T. Nguyen/  
Supervisory Patent Examiner, Art Unit 3731  
3/16/09